REMARKS/ARGUMENTS

Claims 1 – 19 are pending in the application.

Applicants have amended independent claims 1, 14 and 16 in order to address the Examiner's 35 USC § 112 objections, as well as to indicate that the non-implanted, combination probe integrates a transceiver, antenna and power source. Thus, Applicants' claims define a probe that has no external components (see the bottom paragraph on page 3 of the specification), in other words, is a self-contained integrated unit (page 5, line 9, of the specification). Support for these amendments is found in the original specification as follows. The integration of the components is stated on page 5, line 12, of the specification, and is further supported by the aforementioned "self-contained" language in line 9 on page 5, as well as the reference at the bottom of page 3 to the fact that the probe contains no wires or similar external means or surface controls. Support for the antenna component can be found on page 6, line 15, and on page 8, line 17.

Also provided with this amendment are revised declarations for Dr. Jayne and Dr. Wharton that more clearly tie these declarations to the specific features/limitations of Applicants' claims.

CLAIM REJECTIONS – 35 USC § 112

The Examiner has objected to the language "self-applied by a human subject into the human vagina". Applicants respectfully submit that the "self-applied by a human subject" portion is certainly inferred, such as by the language at the top of page 4 of the specification that refers to the use by women of the probe unit "without professional intervention or special training". Certainly at least the language "into the

human vagina" is fully supported by Applicants' specification such as by the language in the paragraph bridging pages 6 and 7, as well as the language on page 7, lines 17 and 18, where it is stated "[s]hould the woman feel any discomfort", as well as the language at the top of page 4 referring to women. The Examiner's attention is also directed to the preamble of claims 1 and 14, where the system and method are limited to humans. Nonetheless, in order to address the Examiner's concerns, the language "self-applied by a human subject" has been deleted from claim 1.

The Examiner has also objected to the language in claim 16 that the probe is "non-expandable and non-compressible in cross-section". Applicants respectfully submit that the specification supports such language by the reference on page 5, line 15, to the material of the unit being polycarbonate, which is known to be a very hard material, having a high impact strength and being used, for example, for ball bearings. Further support can be found on page 6 of the specification, where in lines 8 and 9 reference is made to the electrode rings being flush with the outer surface of the unit. This flush state could be maintained only if the body of the unit were rigid.

The Examiner has also objected to the use of the language "without the use of a tool" in claims 17 – 19. From the language in the sentence bridging pages 6 and 7, where it is stated that the stimulator unit 21 is then inserted into the vagina (similar to a tampon), and from the language on page 6, line 3, namely that the end 24 of the unit 21 is rounded to facilitate vaginal insertion, Applicants respectfully submit that it is self-evident that insertion is accomplished without a tool. This is furthermore supported by paragraph 6 of Dr. Jayne's declaration, where he states that one of

ordinary skill in the art would clearly understand that the device of the present application is to be inserted without the use of a tool.

Finally, the Examiner continues to object to the terminology "non-implanted". Applicants respectfully submit that the cited non-technical and non-medical Tenth Edition of Merriam Webster's Collegiate Dictionary (1996) is hardly a proper reference. Applicants have more than adequately explained the ordinary usage of this term, as understood in the medical field, in previous amendments and have supported such usage by submitting written evidence, including declarations by experts in the field. For example, in paragraph 5 of Dr. Jayne's declaration, he states that the terms "non-implanted", "implant", and terms derived therefrom are all terms of the art. The Examiner's "dismissal" of this aspect of Dr. Jayne's declaration is not understood. Furthermore, the Examiner has provided no reason why the terminology of the industry does not control, as required by MPEP section 2111, which indicates that the PTO is to apply the meaning of words as they would be understood by one of ordinary skill in the art. Applicants respectfully note that the various FDA regulations that were submitted were merely done so to provide support for the fact that the terms used are the usage of those of skill in the art.

Furthermore, contrary to the Examiner's statement near the bottom of page 4 of the present Office Action, there is no contradiction by Applicants' use of the terminology "non-implanted". The reason for the apparent confusion is that the Examiner has incompletely cited the "dictionary" definition of the term "implant", and has hence misinterpreted the application and use of this term and terms derived therefrom. In particular, the actual and complete "dictionary" definition states "to

insert in a living site or living tissue (as for growth, slow release, or formation of an organic union)" and then provides the example of "subcutaneously implanted". Clearly, Applicants' device is in fact a "non-implanted" device, since it does not meet the "dictionary" definition of the word implant. This becomes even more clear from a definition provided by the New Lexicon Webster's Dictionary of the English Language, Encyclopedic Edition, 1989, which provides the definition for the word implant as "(med.) to insert (e.g. a living tissue, as in grafting, or drugs for gradual absorption) beneath the skin" (emphasis added). Hence, Applicants' use of the term "non-implanted" is in fact correct and is clearly understood by those of skill in the art (the Examiner's attention is again directed to the declarations that have been submitted).

Despite the substantial evidence submitted to support Applicants' use of the term "non-implanted", it is respectfully submitted that the issue can be resolved by referring to Merriam Webster's Collegiate Dictionary, where the term "non-" is defined as "a prefix meaning **not**". Thus, Applicants' device is a device that is "not implanted", since it is not subcutaneously inserted in living tissue, i.e. is not beneath the skin. In view of the foregoing, Applicants respectfully request that the Examiner withdraw his rejections concerning the terminology "non-implanted" and derivatives thereof.

CLAIM REJECTIONS – 35 USC § 102

A) The Examiner has rejected claims 1 – 7, 11 – 13, 16, 17 and 19 under 35 USC 102(e) as being anticipated by Mehrotra.

Applicants' amended claims require a combination probe that integrates a transceiver, antenna and power source. Thus, Applicant defines a probe that contains no external means for transmitting and/or receiving information, i.e. Applicants' probe is a self-contained unit.

In contrast, during prosecution of the Mehrotra application, the Examiner in that case indicated that "the prior does not teach or suggest an apparatus for monitoring the estrus-state and/or nonpregnancy of a mammal that includes a housing joined with a transmitting means by a relatively inflexible arm such that, when the housing is within the mammal's vagina, the transmitting means is substantially external and proximal to the mammal's body". Mehrotra, in response to the Office Action where the aforementioned statement appeared, indicated that the claims of his application had been amended such that all claims now include, directly or indirectly, the limitation indicated by that Examiner as not being taught or suggested by the prior art. Mehrotra thus acknowledged and emphasized that his apparatus included a housing that was joined with transmitting means such that when the apparatus was within the mammal's vagina, the transmitting means was substantially external and proximal to the mammal's body. The Examiner's attention is also respectfully directed to Fig. 2 of Mehrotra as well as to the components 28, 24 (external loop antenna) and 30 in Fig. 1, as well as, by way of example only, column 3, line 67, to column 4, line 9, column 5, lines 9 – 12, and of course the claims. Therefore, it is respectfully submitted that Mehrotra does not provide a combination probe which integrates a transceiver, antenna, and power source and hence cannot

teach or suggest the combination probe required by Applicants' claims, as required by MPEP sections 2131 and 2143.03.

Applicants' claims also require that the combination probe, which integrates a transceiver, antenna and power source, be provided with two-way wireless communication means for transmitting information that is transduced and for receiving control and programming signals. It is respectfully submitted that Mehrotra in no way teaches or suggests a combination probe, which integrates a transceiver, antenna and power source, for receiving control and programming signals.

Finally, it is respectfully submitted that Mehrotra is clearly not directed to just any "mammal". Rather, Mehrotra is limited to tailed mammals as is explicitly stated, for example, in the claims, and, by way of example only, in such language as that contained in column 5, line 61, which refers to a cow's or other animal's tail.

B) Claims 1 – 7 and 11 – 13 continue to be rejected by the Examiner under 35 USC 102(e) as being anticipated by Guice. However, Applicants respectfully submit that Guice cannot anticipate Applicants' claims because it does not meet the requirements of MPEP section 2131, namely that it does not teach every element of the claim, and in particular does not show the identical invention "in as complete detail as is contained in the ... claim".

Applicants' claim 1 includes a non-implanted, combination probe, which integrates a transceiver, antenna and power source and is adapted to be inserted into the human vagina. It is respectfully submitted that the limitation of Applicants' claim 1 that the combination probe "is adapted to be inserted into the human vagina" need not result in a structural difference between the claimed invention and the prior

art in order to be considered a distinguishing limitation, as stated by the Examiner. In particular, MPEP section 2173.01 states that Applicant "may use functional language ... or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought". This is followed by the language in MPEP section 2173.05(g), where it is stated in the second paragraph that a functional limitation must be evaluated and considered, just like any other limitation of the claim. Furthermore, this paragraph states that a functional limitation is often used "to define a particular capability" of a recited element. In the in re Barr case cited in the third paragraph of this section of the MPEP, a similar limitation, here "incapable", was found to be "perfectly acceptable because it set definite boundaries on the patent protection sought". Applicants submit that this is precisely the situation afforded by Applicants' limitation that the combination probe "is adapted to be inserted into the human vagina".

In contrast thereto, Guice is not adapted to be inserted into a human vagina. This is the conclusion of both Dr. Wharton, in paragraph 3 of his declaration, and Dr. Jayne, as stated in paragraph 8 of his declaration. This is based in part on the statements made in paragraph 4 of Dr. Jayne's declaration, namely that whereas Guice is clearly limited to use in animals, Applicants' device is for insertion into a human vagina, as required by Applicants' claim 1. Given this claimed difference or defined boundaries as to capability, Dr. Jayne also states in paragraph 4 that one of ordinary skill in the art would not look to Guice for a device that is to be inserted into the human vagina. Dr. Jayne explains that this is very understandable given the

significant anatomical differences between the vaginas of animals, and especially cows, and those of humans.

With regard to the embodiment of Figs. 17 – 19 of Guice, the spring-like compression of this embodiment makes it unsuitable for human use, and as Dr. Jayne states in paragraph 6 of his declaration, one of ordinary skill in the art would never consider that such a device "is adapted to be inserted into the human vagina", as required by Applicants' claim 1. Applicants certainly take exception to the Examiner's dismissal of the declarations of Drs. Jayne and Wharton who, as recognized by the Examiner, have considerable expertise in their respective fields. The Examiner finds their declarations to be not persuasive or not convincing, thus substituting the opinion of one not skilled in the art of the human medical devices that are the subject matter of the instant application for the opinions of experts in the field. The Examiner merely states that the Guice device would be capable of being used in the human vagina, but provides no basis therefor. In contrast, the experts very clearly state that the device of the Guice reference would not be capable of being inserted, in other words not adapted to be inserted, into the human vagina. Applicants respectfully request that the declarations of Dr. Jayne and Dr. Wharton, two highly qualified experts, be given their proper weight.

Applicants' claim 1 also defines the combination probe as being non-implanted. With the possible exception of the embodiment of Figs. 17 – 19, the Guice devices have to be implanted in order to be retained in, and not expelled from, the animal being monitored (see paragraph 7 of Dr. Jayne's declaration). As further support for the fact that the use by Guice of the term "implant" really does mean an

implant, the Examiner's attention is directed to several passages of Guice. For example, on page 16, in paragraph [0159], Guice refers in the second line thereof to "**injection** of telesensor implants". In the top few lines on page 17, reference is made to the promotion of "the **ingrowth** of tissue to help **anchor** the telesensor implant", and to the promotion of "healing and sealing at the point of skin or hide **penetration**". On page 17, paragraph [0166], reference is made to "a portion of the implant **penetrating** the skin or hide of the animal". In addition, further evidence in support of the fact that Guice's **automated animal health monitoring system (AAHMS)** is an implant can be found in Guice's characterization of the reference cited in his paragraph [0034], where it is stated that that patent teaches against the use of implants. The following language regarding "installed within the animal's tissue" demonstrates, however, that Guice believed it was necessary for the devices to be implanted, and then uniformly uses the word "implant" to describe his own devices. Furthermore, even for the embodiments for Figs. 17 – 19, since they require a tool, such embodiments would be considered implants by those of ordinary skill in the art (again see paragraph 6 of Dr. Jayne's declaration).

CLAIM REJECTIONS – 35 USC § 103

A) The Examiner has rejected claims 8 – 10 under 35 USC 103(a) over Mehrotra in view of Eini.

The inapplicability of Mehrotra has been discussed in great detail above. Furthermore, Applicants respectfully submit that Mehrotra is not even analogous art under the guidelines set forth in MPEP section 2141.01(a). As clearly stated in the declarations of both Dr. Jayne and Dr. Wharton, one of ordinary skill in the art would

not find that a reference clearly related to animals could commend itself to solving a problem related to humans. It should also be pointed out that in Eini also, the antenna (here the power source as well) is external to the unit, and not integrated therein as required by Applicants' claims. The Examiner's attention is also directed to Applicants' earlier comments regarding Eini in their amendment dated December 3, 2003.

B) The Examiner has rejected claims 1 – 7 and 11 – 19 under 35 USC 103(a) over Blythe in view of Mehrotra.

The Blythe reference was dealt with in detail in Applicants' amendment dated September 29, 2005, and Blythe, as acknowledged by the Examiner on page 13 of his 12/22/05 Office Action, has an external probe portion, in contrast to Applicants' probe. Furthermore, it is respectfully submitted that neither of the cited references is analogous art. First of all, they are not in the same field of endeavor as is Applicants' device, since they deal with veterinary devices. This is further borne out by the great differences in the PTO classifications given the various devices. Nor are the cited references reasonably pertinent to the particular problem with which the Applicants were dealing. Whereas the Applicants were dealing with the problem of providing an ergonomic, wireless device for humans, the Fig. 5 device of Blythe was for use in veterinary applications, which is also true for the device of Mehrotra.

In addition, since the proposed modification or combination of the cited references would change the principle of operation of the prior art invention being modified, then pursuant to the last section of MPEP 2143.01, the teachings of the references are not sufficient to render the claims prima facie obvious. Finally,

pursuant to the first and third sections of MPEP 2143.01, even if Blythe and Mehrotra could be combined, this is not sufficient to establish prima facie obviousness without a suggestion or motivation in the references to combine them in such a way as to provide all of Applicants' claimed features.

In view of the foregoing discussion, Applicants respectfully request reconsideration of the allowability of Applicants' amended claims. Furthermore, the undersigned respectfully requests a telephone interview in order to discuss appropriate claim language, and possible canceling of claim language and/or even claims, in order to bring the application into condition for allowance.

Respectfully submitted,

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